

Appl. No. 10/803,126  
Docket No. 9183M&  
Amdt. dated June 1, 2006  
Reply to Office Action mailed on December 1, 2005  
Customer No. 27752

## REMARKS

### Claim Status

Claims 1 - 25 are pending in the present application. No additional claims fee is believed to be due.

Claims 10 and 13 are canceled without prejudice.

### Claim Objections

Claim 19 has been amended to correct a typographical mistake regarding the repetition of the phrase "and wherein said zinc hydroxide". The first appearance of this phrase has been deleted. Claims 2 and 3 have been amended to change 'ZPT' to "zinc pyrithione" for the purposes of clarity. Support for this amendment is found at page 5, line 27 of the specification.

### 35 USC §112 Rejections

Claim 1 has been rejected under §112, second paragraph, as the Office Action asserts this claim as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has asserted that it is unclear what constitutes an "effective amount". In light of this rejection, Claim 1 has been amended to incorporate the matter of Claims 10 and 13. Claim 1 has been further amended to recite "weight% based on the total weight of the composition". Support for this amendment is found at page 3, lines 22-25 and 31 of the specification.

Claims 10 -14 has been rejected under §112, second paragraph, as the Office Action asserts that these claims are indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. In light of this rejection, Claims 11, 12 and 14 have been amended to recite "weight% based on the total weight of the composition". Support for this amendment is found at page 3, lines 22-25 and 31 of the specification.

Claims 10 and 13 are canceled without prejudice.

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Claim 21 has been amended to delete the term in component (c) "or" and add the term --and-- and further defines the present invention. Support for this amendment is found in the claims as originally filed and in the specification on page 4, line 11 to page 5, line 20.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

**Rejection Under 35 USC §102(b) Over WO 01/00151 (Gavin et al.)**

Claims 1-17 and 23-25 have been rejected under 35 USC §102(b) as being anticipated by International Patent Application No. WO 01/00151 to Gavin, et al (hereinafter "Gavin et al.").

Gavin, et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, the composition of Gavin, et al. includes from about 0.001% to about 10% by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione, from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts and mixtures thereof and a topical carrier for the anti-microbial active and the metal salt.

In contrast, the instantly claimed invention is directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1. Gavin et al. does not disclose or suggest an augmentation factor for any purpose, much less a composition having an augmentation factor greater than 1. The Office Action asserts that the claimed augmentation factor is inherently disclosed in Gavin et al.

The Office Action asserts that it interprets zinc carbonate to be synonymous with basic zinc carbonate as defined in the instant specification. The Office Action asserts that the zinc-containing layered material (zinc carbonate) is present from 0.001% to 10% by weight of the composition preferably 0.1% to 2% by weight and in a ratio of to the antimicrobial active agent (zinc pyrithione) from about 5:100 to about 5:1. The Office Action asserts that since the composition is the same and in the same proportions as the instantly claimed invention, then the composition of Gavin et al. would inherently have

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an augmentation factor of greater than 1. The Office Action further asserts that the Patent & Trademark Office is not equipped with the scientific equipment to compare the composition of Gavin et al. to the instantly claimed invention but when the compositions are comprised of the exact same materials and would inherently have the exact same properties then the burden is appropriately shifted to the Applicant to demonstrate unexpected results otherwise. However, Applicants do not concede that the instantly claimed materials are the same as those of Gavin et al.

Therefore, Applicants respectfully submit a Declaration of James R. Schwartz under 37 CFR 1.132. Dr. Schwartz is one of the named inventors of the present invention. The 1.132 Declaration demonstrates that zinc carbonate is structurally different from basic zinc carbonate. In contrast, the data in the 1.132 Declaration demonstrates that zinc carbonate and basic zinc carbonate are both well-defined chemical entities with quite different properties, as reflected in Table 1 and the phase diagram provided. This is further demonstrated by the fact that zinc carbonate and basic zinc carbonate have assigned different CAS numbers (Chemical Abstract Services). Further, zinc carbonate has a molecular structure that is not considered to be lamellar, or layered, wherein basic zinc carbonate is a layered structure. Thus, zinc carbonate is not a "zinc layered material" as is recited in the instant claims.

Further, as zinc carbonate has been demonstrated to be structurally different from basic zinc carbonate, the composition of the instantly claimed invention is not the same as the composition of Gavin et al. Therefore, the composition of Gavin et al. would not inherently have an augmentation factor of greater than 1, as is recited in the instant claims.

Therefore, when one compares the composition of Gavin et al. to the instantly claimed invention, the compositions are not comprised of the exact same materials and would not inherently have the exact same properties, as demonstrated in the 1.132 Declaration.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

**Rejection Under 35 USC §102(b) Over US 4,943,432 (Biener)**

Claim 22 has been rejected under 35 USC §102(b) as being anticipated by US 4,943,432 to Biener (hereinafter "Biener").

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Biener discloses a composition for the treatment of psoriasis and other skin diseases. The composition is composed primarily of a mixture of magnesium halide, such as magnesium chloride, with mixed alkali and alkaline earth metal salts such as sodium and potassium chloride and/or bromide and calcium chloride or bromide. Other cations present in the composition include: strontium, aluminum, iron, lithium, and zinc. Anions present in the compound include: sulphate, hydrogen carbonate, borate, fluoride, silicate, iodide and carbonate. The salt mixture was made to duplicate the components found in the water of the Dead Sea.

In contrast, Claim 22 is directed to a process for preparing a zinc hydroxycarbonate-containing composition. The process includes reacting a carbonate or bicarbonate salt with a zinc compound causing in-situ formation of the carbonate salt with the zinc salt to form zinc hydroxycarbonate.

While Biener does disclose a composition that contains carbonate and zinc, the composition contains a number of other components that may react with the zinc and carbonate to prevent, or impede, the formation of zinc hydroxycarbonate. There is no suggestion in Biener that the components of the composition react to form zinc hydroxycarbonate in situ.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

**Rejection Under 35 USC §102(b) Over US 4,933,101 (Cilley et al.)**

Claim 22 has been rejected under 35 USC §102(b) as being anticipated by US 4,933,101 to Cilley et al. (hereinafter "Cilley et al.").

Cilley discloses liquid automatic dishwashing detergent compositions containing an insoluble zinc salt useful for inhibition of glassware corrosion in the dishwasher.

In contrast, claim 22 is directed to a process for preparing a zinc hydroxycarbonate-containing personal care composition. It is noted that Cilley is directed to a field of art outside the claimed invention. More specifically, Cilley relates to dishwashing detergent compositions, while claim 22 relates to personal care compositions.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

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**Rejection Under 35 USC §103(a) over US 4,161,526 (Gorman) in view of US  
3,960,782 (Daley)**

Claims 18-21 have been rejected under 35 USC §103(a) as being unpatentable over US 4,161,526 to Gorman (hereinafter "Gorman") in view of US 3,960,782 to Daley (hereinafter "Daley").

In order to establish a prima facie cast of obviousness, the Examiner must show that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there is a reasonable expectation of success, and (3) all of the limitations of the claims are taught or suggested in the prior art (M.P.E.P. 2143).

Gorman discloses pyrithione, pyrithione or dipyrithione compositions containing the zinc salt of an organic or an inorganic acid, zinc hydroxide or zinc oxide or a mixture thereof for the prevention or removal of discoloration in the compositions.

Daley discloses shampoo compositions which impart luster and manageability to hair. The compositions comprise an alkyl sulfate or alkyl monoglyceride sulfonate surfactant, urea, dodecyl alcohol and guanidine or a water-soluble salt thereof. The compositions have a pH or from about 5 to about 8.

In contrast, Claim 18, and the claims dependent therefrom, relate to a process for preparing a basic zinc carbonate-containing personal care composition. The process includes reacting a carbonate or bicarbonate salt that is soluble in the personal care composition with a zinc compound that is soluble or insoluble in the personal care composition. The reaction causes in-situ formation of the carbonate salt with the zinc salt to form zinc hydroxycarbonate in the zinc hydroxycarbonate-containing personal care composition.

Neither Gorman nor Daley disclose or suggest a zinc hydroxycarbonate-containing personal care composition much less a process for reacting a carbonate or bicarbonate salt that is soluble in the personal care composition with a zinc compound to form zinc hydroxycarbonate in situ. Additionally, there is no motivation to combine these two references. Moreover, combination of these references would not result in the presently claimed composition, but rather a discoloration-free composition (Gorman) that contains Daley's disclosed additives to impart luster and manageability to the hair.

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Therefore, no *prima facie* case of obviousness has been established. Applicants respectfully request reconsider and withdraw this rejection under 35 USC §103(a).

*The Double Patenting Rejection*

I. Claims 1, 8, 9, 13, 14 and 23-25 are provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1, 11, 12, 38-42 and 51-53 of copending Application No. 10/742,557.

Claim 1 of the copending Application 10/742,557 discloses a composition comprising a particulate zinc material wherein the particulate zinc material has a crystallite size less than about 600 Å.

In contrast, the instant invention is directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1.

The Office Action asserts that one of ordinary skill in the art would have recognized that the compositions have the same components in the same ratios and would have the same augmentation factor. The selection of the size of the particulate zinc material (i.e. crystallite size of less than about 600 angstroms) has been deemed merely a matter of judicious selection and routine optimization.

However, crystallite size is not within the purview of the skilled artisan to determine the optimal physical properties such as crystallite size. Crystallite size cannot be systematically adjusted during the course of routine experimentation to obtain desired relative zinc lability. A crystallite is a domain of solid matter that has the same structure as a single crystal. The crystallite size is a property of the way the material has been produced and cannot be altered substantially afterwards by physical methods. The crystallite size analysis in the 10/742,557 and data on pages 33-36 of the specification demonstrate the results which are not merely routine optimization. Clearly, the present application does not substantially overlap in scope with regard to the crystallite size or the results regarding crystallite size as discussed in the specification of 10/742,557. The claims of the present application are patentably distinct from those of Application 10/742,557.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

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II Claims 1, 5-9, 13 and 23-25 are provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-3, 5, 14-17 and 23-24 of copending Application No. 10/802,166.

Claim 1 of the Application 10/802,166 is directed toward a composition comprising an effective amount of zinc-containing layered material; an effective amount of a surfactant including a surfactant with an anionic functional group; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

In contrast, the instant invention is directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1. The currently claimed invention is not directed to a composition containing a surfactant with an anionic functional component. Further, the currently claimed invention is not directed to a composition comprising a required relative zinc lability of greater than about 15% for a zinc-containing layered material. Application 10/802,166 demonstrates that it not inherent to have the same characteristics with regard to anionic surfactant systems and its effect on lability, as demonstrated in the data found in specification on page 31.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

III. Claims 1, 5-8, 13 and 23-25 25 are provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-3, 9, 18-21 and 26-28 of copending Application No. 11/100,648.

Claim 1 of copending Application 11/100,648 discloses a composition comprising an effective amount of zinc-containing layered material; an effective amount of a surfactant including a surfactant with an anionic functional group; an effective amount of a cationic polymer wherein the cationic polymer has a trimethylamine level of less than about 45 ppm; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further wherein the composition has a pH of greater than about 6.8.

In contrast, the instant invention is directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1. The currently claimed invention is not directed to a composition containing a cationic polymer wherein the cationic polymer has a trimethylamine (TMA) level of less than about 45 ppm. Further, the currently claimed invention is not directed to a composition

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comprising a surfactant with an anionic functional group. Further, the currently claimed invention is not directed to a composition comprising a required relative zinc lability of greater than about 15% for a zinc-containing layered material with a required pH of greater than 6.8.

The Office Action asserts that the addition of the cationic polymer is suggested by Bowser et al (US 5,723,112) and that the selection of the polymer is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art. However, it is not a routine optimization in Application 11/100,648 for the discovery that, in order to produce an acceptable composition having a pH of greater than 6.8, which comprises a cationic polymer, with low to no amine off-odor, that it may be necessary to use a cationic polymer which contains from no detectable TMA to low levels of TMA. Such disclosure is found in the specification of Application 11/100,648 at pages 18, line 10 to page 22, line 22. The instant claims and those of Application 11/100,648 are patentably distinct.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

IV. Claims 1, 5-9, 13 and 23-25 25 are provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-3, 7, 8-21 and 30-32 of copending Application No. 11/216,520.

Claim 1 of the copending Application 11/216,520 discloses a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a surfactant with an anionic functional group; wherein the particulate zinc material has a relative zinc lability of greater than about 15%; and wherein the composition comprises less than 5.5 micromoles of a zinc binding material per gram of the particulate zinc material/per m.sup.2/gram surface area of the particulate zinc material.

In contrast, the instant invention is directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1. The currently claimed invention is not directed to a composition wherein the composition comprises less than 5.5 micromoles of a zinc binding material per gram of the particulate zinc material/per m.sup.2/gram surface area of the particulate zinc material.

Further, the currently claimed invention is not directed to a composition comprising a surfactant with an anionic functional group. Further, the currently claimed



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invention is not directed to a composition comprising a required relative zinc lability of greater than about 15% for a zinc-containing layered material.

The Office Action asserts that the selection of surfactants and zinc binding material is deemed merely a matter of judicious selection and routine optimization. The Office Action further asserts that the specification of 11/216,520 points out that citric acid can be a zinc binding material (page 11, lines 3-6) and further asserts that Brower et al (US 5,723,112) suggest addition of pH adjusting agents and further Cardin et al (US 5,104,645) includes citric acid as a pH adjusting agent.

However, Application 11/216,520 is directed toward and claims the findings that materials which have a high affinity for zinc and have the tendency to result in the formation of insoluble complexes of zinc can foul the surface of particulate zinc materials (PZM's). By "fouling" it is meant the formation of an insoluble surface layer of the *zinc binding material* (ZBM) zinc salt which interferes with the kinetic lability of zinc from the base PZM material. The magnitude of negative effect of ZBM's is the product of the strength of association to zinc and the relative amount of the ZBM (relative to the PZM surface area). Other raw materials may contain relatively low levels of ZBM's that are added for a secondary benefit. For example, *citric acid* is commonly used for pH control during raw material manufacture. It is not always obvious to the end user of a raw material if such ZBM's are present; this information can be obtained from the manufacturer or analyzed directly. However, in the copending application 11/216,520, ZBMs, such as citric acid, are meant to be avoided or limited in use to the claimed limitation of "less than 5.5 micromoles of a zinc binding material per gram of the particulate zinc material/per m.sup.2/gram surface area of the particulate zinc material".

Therefore, clearly the limitation of zinc binding materials, due to their "fouling" of the surface of particulate zinc materials is clearly patentably distinct from the present claims.

The instant claims and those of copending Application 11/100,648 are patentably distinct. Applicants respectfully request reconsideration and removal of this double patenting rejection.

V. Claims 1, 8, 9 and 13 are rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1, 3 and 5 of U.S. Patent No. 6,908,912 (hereinafter '912).

Claim 1 of the '912 patent relates to an antimicrobial composition concentrate comprising pyrithione or a pyrithione complex in an amount of from about 0.05% to

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about 20 weight percent, a zinc source in an amount of from about 0.01% to about 5%, and an organic amine component in an amount of from about 30% to about 80%. Zinc carbonate and be the source of zinc ion (Claim 5).

In contrast, the instant invention is directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1. The currently claimed invention is not directed to a composition containing an organic amine component. Further, as provided in the attached 1.132 Declaration of James R. Schwartz, applicants have established that zinc carbonate, as disclosed in the '912, is not synonymous with basic zinc carbonate, a zinc containing layered material, of the present invention. And therefore, the compositions would not inherently have the same characteristics including augmentation factor.

Applicant's respectfully request reconsideration and withdrawal of this nonstatutory obviousness-type double patenting.

#### Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC § 112, 102 and 103. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-9, 11-12, and 14 - 25 is requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

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